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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/448,356	11/23/99	BURDICK	D 20257/110665

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HM12/0828

EXAMINER

GAZI, S

ART UNIT	PAPER NUMBER
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1616

DATE MAILED:

08/28/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/448,356

Applicant(s)

Burdick et al.

Examiner

Sabiha Qazi

Group Art Unit

1616



☒ Responsive to communication(s) filed on Jul 17, 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-6 and 8-23 is/are pending in the application.

Of the above, claim(s) 9-23 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-6 and 8 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims 9-23 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 3 and 4

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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Non final Action on Merits

Status of the Application

Claims 1-6 and 8-23 are pending.

Claims 1-6 and 8 are rejected.

Claim 7 is cancelled.

Claims 21-23 are added.

Claims 9-23 are withdrawn from consideration as non elected invention.

Rejection Withdrawn

Claims 1-8 rejected under 35 U.S.C. 102(b) as being anticipated by Meittinen et al. (US Patent 5,502,045), lines 31-38, col. 4, lines 44-67, col. 4; claims 1, 5 and 6 and Eugster et al. (CA 120:245603 abstract of CH 681891) are withdrawn because claim 7 is cancelled and other claims are amended.

Rejection Maintained

Claims rejected as being anticipated by WO 92/19640 lines 4-6, page 5; lines 8-37, page 6; Claims 1, 5 and 6 is maintained

Claims are amended but claims 1-7 are still considered anticipated, see lines 20-24, page 10; lines 22-30, page 9.

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Response to Arguments

Applicant's response has been fully considered but are not found persuasive. Following reasons apply.

1. Arguments are based on amended claims. Note, that rejection was made on original claims before the amendments therefore, comments on 102 rejection are not relevant. Why the response is drawn towards newly amended claims which were not examined. It is well understood that claims are amended to overcome 102 rejection.

2. Applicant's argue regarding the restriction requirement. The basis of the arguments is that The basis of the argument is that all the invention should be examined in this application and it will not be a burden on the Examiner. The traversal is on the grounds that there is no serious burden to support the restriction. Examiner respectfully disagree with the arguments, following reasons apply.

1. The examiner has given the reasons as to distinctness of each invention, that search required for one group will not be the same for any other group and thus, a reference against one invention may not be applicable against the other invention.

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They are patentably distinct.

Instant invention is drawn to separate inventions which require separate searches, and are not art recognized equivalents. For example the search for the invention of group I would be different from the search for any other group.

Furthermore, a reference used to reject the invention of group I will not be used to reject the invention of group II.

Burden is likewise demonstrated by divergent classification and database search for the entire genus would represent excessive burden on the examiner.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper. It would be an undue burden on the Examiner to search all the invention claimed in this application.

There are multiple inventions in one application and it would be a burden to examine all the invention in a proper way for the reasons cited above. For the same reasons restriction requirement is considered proper and restriction is made FINAL.

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3. Applicant's argue that claims 15 and 16-20 are process claims and therefore claim 15 in a separate group is an error. Examiner very well know that claim 15 is a process claim. The reason to keep claim 15 and 16-20 in separate groups due to the different process in claim 15 and 16-20. Therefore this not an error.

4. Applicant's argue that in 102 rejection the "identity of invention" was not made. Examiner respectfully disagree, applicant is requested to see the office action under 102 rejection where lines and cols were indicated.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 8 is improperly dependent on claim 1. Claim 8 does not further limit claim 8.

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Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claim 1-4 rejected under 35 U.S.C. 102(b) as being anticipated by Shimada et al. (JAOCs, Vol. 76, No. 6, (1999), pages 713-716).

See Table 3 on page 716 where esterification of sitosterol (which is a phytosterol) are disclosed. Fatty acid is the same as has claimed in amended claim 1, i.e. docosaheptaenoic acid and eicosaheptaenoic acid.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claim(s) 1-6 and 8 are rejected under 35 U.S.C. 103 as being unpatentable Novak Egon WO 00/04887. See the entire document especially and lines 5-14 on page 10; last para on page 11; claims 1-11.

Novak Egon (WO 00/04887) teaches phytosterol and/or phytostanol esters compositions. The aliphatic acid may be selected from either straight chain of branched unsaturated or saturated fatty acids, (1st two lines of last para on page 11).

Instant claims differ from the reference in claiming specific fatty acids i.e. docosahexaenoic acid and eicosahexaenoic acid where as prior art teaches that aliphatic acid may be selected from either straight chain of branched unsaturated or saturated fatty acids. Instant claims are a selection of prior art teachings.

It would have been obvious to one skilled in the art to prepare additional beneficial composition by selecting specific docosahexaenoic acid and eicosahexaenoic acid from fatty acid taught by the prior art. There has been ample motivation provided by the prior art to prepare the instant invention by teaching unsaturated fatty acids and esters. Instant compositions would have been obvious at the time of invention.

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The subject as instantly claimed would have been obvious to one at the time of invention.

It would have been obvious to prepare additional beneficial compositions as disclosed by the prior art.

Even if applicant's modification results in great improvement and utility over prior art, it may not be patentable if the modification was within the capabilities of one of the skilled in the art. More particularly, when the general conditions of the claim are disclosed by the prior art, it is not inventive to discover optimum or workable ranges by routine experimentation. In re Aller et al. 105 USPQ 233.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill might reasonably infer from the teachings. *In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA 1976). A reference is not limited to working examples. *In re Fracalossi* 215 USPQ 569 (CCPA 1982).

Accordingly, the burden of proof is upon applicants to show that instantly claimed subject matter is different and unobvious over those taught by prior art. See *In re Brown*, 173 USPQ 685,

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688; *In re Best*, 195 USPQ 430 and *In re Marosi*, 218 USPQ 289, 293.

In the light of the forgoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the instant claims would have been obvious within the meaning of 35 U.S.C. 103(a).

The data showing any unexpected results would overcome the above 35 U.S.C. 103(a) rejection.

2. Claim(s) 1, 5, 6 and 8 are rejected under 35 U.S.C. 103 as being unpatentable over Miettinen et al. (WO 92/19640). See the entire document especially lines 22-30, page 9 and lines 20-24, page 10; lines 4-6, page 5; lines 8-37, page 6 in WO '640.

Miettinen et al. teaches a composition of β -sitostanol fatty acid ester or fatty acid ester mixture. The reference also teaches fatty acid mixture containing 2-22 carbon atom and esterification of sitostanol. See claims 1-3.

Instant claims differ from the reference in claiming specific fatty acids i.e. docosahexaenoic acid and eicosahexaenoic acid where as prior art teaches fatty acids especially containing approximately 2-22 carbon atoms (lines 20-

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24, page 10). Instant claims are a selection of prior art teachings.

It would have been obvious to one skilled in the art to prepare additional beneficial composition by selecting any fatty acids for example, docosahexaenoic acid and eicosahexaenoic acid from fatty acid 2-22 carbon atoms taught by the prior art. There has been ample motivation provided by the prior art to prepare the instant invention. Instant compositions would have been obvious at the time of invention.

The subject as instantly claimed would have been obvious to one at the time of invention.

It would have been obvious to prepare additional beneficial compositions as disclosed by the prior art.

Even if applicant's modification results in great improvement and utility over prior art, it may not be patentable if the modification was within the capabilities of one of the skilled in the art. More particularly, when the general conditions of the claim are disclosed by the prior art, it is not inventive to discover optimum or workable ranges by routine experimentation. In re Aller et al. 105 USPQ 233.

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Accordingly, the burden of proof is upon applicants to show that instantly claimed subject matter is different and unobvious over those taught by prior art. See *In re Brown*, 173 USPQ 685, 688; *In re Best*, 195 USPQ 430 and *In re Marosi*, 218 USPQ 289, 293.

In the light of the forgoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the instant claims would have been obvious within the meaning of 35 U.S.C. 103(a).

The data showing any unexpected results would overcome the above 35 U.S.C. 103(a) rejection.

Telephone Inquiry Contacts

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sabiha N. Qazi, whose telephone number is (703) 305-3910. The examiner can

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normally be reached on Monday through Friday from 8 a.m. to 6 p.m. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.



Sabiha N. Qazi Ph.D.

8/25/00

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